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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WEDDINGTON, KEVIN E	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/571,466	RUECKLE ET AL.	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-39* is/are pending in the application.

4a) Of the above claim(s) *26-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3-13-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 11-39 are presented for examination.

Applicants' preliminary amendment and information disclosure statement filed March 13, 2006 have been received and entered.

Applicants' election filed August 16, 2007 in response to the restriction requirement of July 17, 2007 has been received and entered. The applicants elected the invention described in claims 11-25 (Group I) with traverse.

Applicants' traverse is not deemed persuasive for reasons set forth in the previous Office action dated July 17, 2007; therefore, the restriction requirement is hereby made Final.

Claims 26-39 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of copending Application No. 10/070,954; over claims 1-27 of copending Application No. 10/088,074; over claim 1 of copending Application No. 10/088,090; over claims 1-8 and 14 of copending Application No. 10/381,197; over claims 1-8 and 14 of copending Application No. 10/381,200; over claims 1-10, 12 and 16 of copending Application No. 10/381,665; over claims 1-11 and 17 of copending Application No. 10/484,744. Although the conflicting claims are not identical, they are not patentably distinct from each other because the seven copending applications teach sulfonamide derivatives and compositions comprising sulfonamide derivatives of formula I (A product), and the present application teaches method of use claims containing the instant sulfonamide derivatives of formula I of the seven copending applications therein which makes the method claims of the present application an obvious variation of the seven copending applications.

Claims 11-25 are not allowed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a written description rejection the

A lack of adequate written description issue arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

In particular, the specification as original filed fails to provide sufficient written bases of any of the agents demonstrating wherein possession of use of the broad terms, an aldose reductase inhibitor, an alpha-glucosidase inhibitor, a sulfonyl urea agent, a biguanide, a thiazolidine, a PPARs agonist, and a GSK-3 inhibitor. The mere fact that Applicant may have discovered one type of drug to be an aldose reductase inhibitor, an alpha-glucosidase inhibitor, a sulfonylurea agent, a biguanide, a thiazolidine, a PPARs agonist, and a GSK-3 inhibitor is not sufficient to claim the entire genus.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

The applicants may want to read the enclosed cited reference, "Biguanide-Wikipedia, the free encyclopedia", which shows various biguanide compounds such as phenformin and buformin were withdrawn from the market due to toxic effects.

Claim 23 is not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1,088,821 A1 (AN) of PTO-1449; hereby known as Arkinstall as evidence by Bennett et al., "JNK: A new therapeutic target for diabetes", Current Opinion in Pharmacology, Vol. 3, No. 4, pp. 420-425, 2003 (AS) of PTO-1449.

Arkinstall teaches pharmaceutically acid sulfonamide derivatives (same as applicants' claim 1) wherein Ar1 is substituted or unsubstituted aryl or heteroaryl group; n is an integer from 0 to 5; and Y is an unsubstituted or a substituted 4-12-membered saturated cyclic or bicyclic alkyl containing at least one nitrogen atom, wherein one nitrogen atom in said ring is bonded to the sulfonyl group of the formula thus providing the sulfonamide (see the abstract). Note the instant compounds are effective modulators (inhibitors) of the JNK pathway. Note on page 15, section

[0110] shows the modes of administration of the instant derivatives such as oral, rectal, transdermal, subcutaneous, intravenous, intramuscular and intranasal.

Bennett et al. teach the JNK pathways have a connection with insulin resistance and type-II diabetes (see page 420, under **JNK, TNF and insulin resistance**). Also note page 422, column 1, second paragraph, states that the JNK pathway is a novel target for the treatment of diabetes and obesity. Finally, on page 423, column 2, first paragraph, states that JNK inhibitors have the potential to show long-term benefit in diabetes by protecting pancreatic islet cells from apoptosis, in turn allowing increased insulin secretion and prevention of hyperglycemia.

Clearly, the administration of the JNK inhibitors derived from the sulfonamides of formula I set forth in Arkinstall would inherently treat metabolic disorder mediated by insulin resistance or hyperglycemia since Bennett et al. teach the JNK pathway inhibitors will treat diabetes, insulin resistance and hyperglycemia.

Claims 11-22 and 25 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1,088,821 A1 (AN) of PTO-1449, hereby known as Arkinstall in view of Sterne (3,174,901) and Weber et al. (3,454,635).

Arkinstall was discussed above supra for the use of sulfonamide derivatives of formula I to treat metabolic disorders mediated by insulin resistance by the inhibition of the JNK pathway (the JNK pathway is known to cause diabetes and obesity, See Bennett et al., *Curr. Op. Pharm., 3(4), pp, 420-425*).

The instant invention differs from the cited reference in that the cited reference does not teach the addition of other supplementary drugs as set forth in claims 23 and 24. One of the secondary references, Sterne, teaches metformin as a well-known anti-diabetic agent used to treat type-II diabetes. The second of the secondary reference, Weber et al., teaches benzenesulfonyl-urea compounds such as glyburide, are well-known anti-diabetic agents too.

Clearly, one skilled in the art would assumed the combination of two individual agents, well-known to treat diabetes, into a single composition would give an additive effect in the absence of evidence to the contrary.

Claims 23 and 24 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm-9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
Art Unit 1614

K. Weddington
August 19, 2007